

thereof unless it is exempt under section 801(d) of the act or § 433.12, § 433.13, § 433.14, § 433.16, or § 433.17, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt.

When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit. Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502(l) of the certification requirements of section 512(n) of the act or is exempt under section 801(d) of the act or § 433.12, § 433.13, § 433.14, § 433.16, or § 433.17, or, if certification is refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502(l) of the act or is exempt under section 801(d) of the act or the certification requirements of section 512(n) of the act or § 433.12, § 433.13, § 433.14, § 433.16, or § 433.17, or, if certification has been refused, unless such shipment or delivery is reproc-

essed and certified or destroyed within a reasonable time.

[39 FR 18939, May 30, 1974, as amended at 41 FR 48267, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977]

**§ 433.16 Exemption for repacking.**

(a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be repacked at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding such establishment from the requirements of section 502(l) of the act or the certification requirements of section 512(n) of the act if the labeling of each container bears the batch mark of the drug and the number of units per package, and if the person who introduces such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for repacking in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such repacking is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of each shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such repacking; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such disposition, and that he will accord full opportunity to such

officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the repacking is completed that he will request certification of each batch thereof unless it is exempt under section 801(d) of the act or § 433.12, § 433.13, § 433.14, or § 433.17, and that he will not remove any of such drug from such establishment unless it complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is so exempt or is returned to him for labeling or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

When the Commissioner finds that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit. Any person who contests the denial or revocation of a permit shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is exempt under section 801(d) of the act or § 433.12, § 433.13, § 433.14, or § 433.17, or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who in-

troduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502(l) of the act or the certification requirements of section 512(n) of the act or is exempt under section 801(d) of the act or § 433.12, § 433.13, § 433.14, or § 433.17, or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

[39 FR 18939, May 30, 1974, as amended at 41 FR 48268, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977]

#### **§ 433.17 Exemption for investigational use.**

A shipment or other delivery of an antibiotic drug shall be exempt from section 502(l) of the act or the certification requirements of section 512(n) of the act if all the procedures outlined in part 312 or § 511.1 of this chapter are complied with. For the purposes of this section, the references in part 312 or § 511.1 of this chapter to "new drug" and "approved new animal drug application" shall be deemed to read "antibiotic drug" and "approval for certification or exemption from certification" respectively.

[39 FR 18939, May 30, 1974, as amended at 40 FR 13497, May 27, 1975; 55 FR 11582, Mar. 29, 1990]

### **Subpart C—Specific Use Exemptions**

#### **§ 433.20 Antibiotic drugs for isolation and differentiation of microorganisms in clinical use.**

Antibiotic drugs subject to section 507 of the act shall be exempt from section 502(l) if such drugs are:

(a) Paper discs impregnated with antibiotics in the amounts listed in the following table: